

REMARKS

Claims 1-13 were pending. Applicants amend claims 1 and 2 above. Accordingly, claims 1-13 are being examined.

Support for amended claims 1 and 2 may be found in the specification as originally filed at page 20, lines 7-10 and page 23, lines 28-31.

Entry of these amendments and the foregoing remarks in the file of the above-captioned patent application is respectfully requested.

REJECTION OF THE CLAIMS UNDER 35 U.S.C. §102(b)

In items 3-4, at page 2 of the Office Action, the Office rejects claims 1-4, 6 and 13 under 35 U.S.C. §102(b), as allegedly anticipated by Lindberg et al. (of record)

Applicants respectfully disagree for the reasons that follow.

The Legal Standard for Novelty

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984). Each and every element of the claimed invention must be disclosed in a single prior art reference in a manner sufficient to enable one skilled in the art to reduce the invention to practice, thus placing the invention in possession of the public. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied* 469 U.S. 851, 105 S.Ct. 172 (1984); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576-7 (Fed. Cir. 1991), *clarified, on recons.*, 1991 U.S.App. LEXIS 33,486 (Fed. Cir. 1991). The absence of

even a single element from a prior art reference negates anticipation. *Atlas Powder Co. v. E. I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984).

Applicants have met the Legal Standard for Novelty

Lindbergh does not expressly or inherently anticipate the presently claimed methods:

The claims have been amended to methods for reducing excess extracellular fluid in hypertensive subjects undergoing hemodialysis.

Lindbergh administered lysine vasopressin (LV) in hypotensive patients (i.e., patients with HIH (hemodialysis induced hypotension). Additionally, Lindbergh does not teach reducing excess extracellular fluid in a hypertensive subject undergoing hemodialysis.

Lindbergh do not expressly anticipate the claimed methods, because Lindbergh do not expressly or inherently disclose treating a “hypertensive subject.”

Therefore, Lindbergh cannot form the basis for an anticipation rejection under §102. Accordingly, Applicants respectfully request that the Office reconsider and withdraw the rejections to claims under 35 U.S.C. §102.

REJECTION UNDER 35 U.S.C. §103(a)

The Office rejects claims 1-13 under 35 U.S.C §103(a), as allegedly unpatentable over Lindbergh, in combination with Dagher and WO 88/01163.

Applicants respectfully disagree.

The Legal Standard for 35 U.S.C. §103

As stated in MPEP §2142, three (3) criteria must be met to establish a *prima facie* case of obviousness:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. *Second*, there must be a reasonable expectation of success. *Finally*, the prior art reference must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based upon applicants' disclosure.¹

The teaching or suggestion to make the claimed combination, and the reasonable expectation of success, must both be found in the prior art, not in the Applicants disclosure (*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

Obviousness is a question of law based on findings of underlying facts relating to the prior art, the skill of the artisan, and objective considerations. See *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). To establish a *prima facie* case of obviousness based on a combination of the content of various references, there must be some teaching, suggestion or motivation in the prior art to make the specific combination that was made by the applicant. *In re Raynes*, 7 F.3d 1037, 1039, 28 USPQ2d 1630, 1631 (Fed. Cir. 1993); *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). Obviousness can not be established by hindsight combination to produce the claimed invention. *In re Gorman*, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). As discussed in *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985), it is the prior art itself, and not the applicant's achievement, that must establish the obviousness of the combination.

¹ MPEP §2142, citing *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

The teachings of the references, their relatedness to the field of the applicant's endeavor, and the knowledge of persons of ordinary skill in the field of the invention, are all relevant considerations. See *In re Oetiker*, 977 F.2d at 1447, 24 USPQ2d at 1445-46; *In re Gorman*, 933 F.2d at 986-87, 18 USPQ2d at 1888; *In re Young*, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991). When the references are in the same field as that of the applicant's invention, knowledge thereof is presumed. However, the test of whether it would have been obvious to select specific teachings and combine them, as did the applicant, must still be met by identification of some suggestion, teaching, or motivation in the prior art, arising from what the prior art would have taught a person of ordinary skill in the field of the invention. *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

The Examiner Has Not Established A *Prima Facie* Case Of Obviousness

The Examiner has not established a *prima facie* case of obviousness because not all of the three necessary criteria have been met. Therefore, as discussed below, the pending claims are patentable over the cited references.

A Discussion of the Cited References

Lindbergh

As discussed above, Lindbergh administered lysine vasopressin (LV) in hypotensive patients. Additionally, Lindbergh does not teach reducing excess extracellular fluid in a hypertensive subject undergoing hemodialysis.

Dagher

Dagher is a review article that discloses the pharmacology of vasopressin (VP). Further, Dagher teaches that VP can be administered to constrict BP in a patient's gut in order to reduce portal pressure in the patient's liver thereby interrupting hepatorenal pressure.

Dagher fails to teach what the primary Lindbergh reference fails to teach, namely, the use of VP to treat hypertensive subjects by reducing excess extracellular fluid so as to maintain blood pressure.

WO 88/01163

WO 88/01163 teaches that vasoconstructive substances can be administered topically to mucosa in order to provide radioprotective effect in patients subjected to radiation treatment of tumors. VP is listed as one of the useful vasoconstructive substances in their claimed compositions.

WO 88/01163 fails to teach what the primary reference fails to teach, namely, the use of VP to treat hypertensive subjects by reducing excess extracellular fluid so as to maintain blood pressure.

The Legal Standard has not been met by the Office

The references in combination do not teach all of the claim limitations

The Examiner asserts that the claimed method is an obvious modification of the Lindbergh, Dagher, and WO 88/01163 references. However, as discussed above, the prior art references in combination does not teach or suggest all of the claim limitations, namely, treating hypertensive subjects let alone (as discussed in previous responses) to

treat subjects by reducing excess extracellular fluid so as to maintain blood pressure.

Moreover, even if there were a suggestion or motivation to combine all elements of the claimed invention, there would not have been a reasonable expectation of success for the reasons which follow.

There was no suggestion to modify the prior art in order to obtain the claimed invention.

To establish a *prima facie* case of obviousness, the Examiner must present evidence that one skilled in the art would have been led to arrive at the claimed invention.² Mere unsupported arguments cannot take the place of evidence.³

In this regard, Lindbergh merely suggests that LV can be used in hypotensive patients to alleviate refractory HH, the two secondary references teaches merely that VP can restrict mucosa and the gut. There was no discussion let alone evidence that VP can be used in hypertensive patients to reduce excess extracellular fluid so as to maintain blood pressure during hemodialysis.

There is no evidence that any modification of the prior art would have led to a reasonable expectation of success in practicing the claimed invention.

It would not be enough to imply that, given the capabilities of those skilled in the art, it would have been obvious to try the claimed invention. In *In re O'Farrell*, the Federal Circuit gave examples of what would be obvious to try, but not obvious under 35 U.S.C. §103: "to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it."⁴ *O'Farrell* clarified the

² *Id.*

³ *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658, 661 (CCPA 1979).

⁴ 853 F.2d 894, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

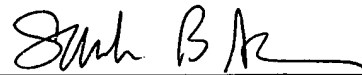
additional requirement for a reasonable expectation of success.

The Examiner has not provided evidence that the prior art teaches or suggests *as a whole* the claimed methods. The claimed methods cannot be obvious over the cited references, because there was no suggestion regarding how to modify the prior art, in order to achieve the claimed methods. Moreover, even if it were obvious to try the combination of elements claimed, without a reasonable expectation of success, a *prima facie* case of obviousness cannot be made. It is therefore, respectfully requested that the rejection under 35 U.S.C. §103, be withdrawn, and that the claims be allowed.

In view of the aforementioned discussion, Applicants respectfully request that the Patent Office reconsider and withdraw the rejection of claims 1-13, under 35 U.S.C. §103.

No fee, other than the \$510.00 three-month extension fee, is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, Applicants hereby authorize the Patent Office to charge the amount of any such fee to Deposit Account No. 50-0306.

Respectfully submitted,



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